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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
COTTON, ABIGAIL MANDA	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 01/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/696,635	TAUTVYDAS ET AL.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *31 August 2005 and 16 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-37,39-45 and 52-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-37, 39-45 and 52-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the amendment received on November 16, 2005. Claims 33-37, 39-45 and 52-54 are pending in the application and are examined on the merits herein.

Applicant's arguments, submitted November 16, 2005, with respect to the rejection of claims 31-37, 39-49 and 50-51 under 35 U.S.C. 112, second paragraph, as being indefinite, have been fully considered and are persuasive. In particular Applicant's cancellation of claims 31-32, 46-49 and 50-51, and Applicant's amendments to claims 33-37 and 39-42 overcomes the rejection of these claims and the claims depending therefrom under 35 U.S.C. 112, second paragraph. Accordingly, the rejection of the remaining claims 33-37 and 39-45 under 35 U.S.C. 112, second paragraph, is withdrawn.

Applicant's arguments submitted November 16, 2005, with respect to the rejection of the claims under 35 U.S.C. 103(a) have been fully considered but they are not persuasive. The following rejections are necessitated by Applicant's amendments to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33-37, 39-45 and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,098,694 to Komp et al. (of record) in view of U.S. Patent No 5,460,833 to Andrews et al. (of record) or U.S. Patent No. 5,569,461 to Andrews et al. (of record.)

Komp et al. discloses a natural deodorant composition comprising (i) the instant fatty acid monoester, glyceryl laurate (also called glycerol monolaurate, as in claim 43) in 0.5-5 wt%, 0.5-3 wt% or 0.5-1.5 wt%, within the claimed range recited in claim 41 (see abstract, column 1, lines 63-68 through column 2, lines 1-2, in particular); (ii) the instant enhancer benzoic acid in an amount of 0.1-0.5, which closely overlaps with the range recited in claim 41; and (ii) a vehicle, such as water (see column 2, line 38, in particular.)

Regarding claims 52-54, Komp teaches providing surfactants (emollients) such as PPG-15 stearyl ether, PPG-15 laureth 5, and PPG/PEG fatty alcohol ethers in an

amount of 2.0-10 wt% (see column 2, lines 36-40 and 64, in particular), which meets and/or overlaps with range limitations recited in the claims.

Regarding claims 33, 36, 39, 40 and 45, Komp teaches the composition can comprise a vehicle such as an alcohol including ethanol (see column 2, lines 30-40 and 50-60, in particular), and thus teaches that the antimicrobials can be diluted, and can comprise an acid such as citric acid (see column 2, lines 9-15, in particular), which is a flavorant.

Komp also discloses that the natural deodorant composition possesses antimicrobial or antibacterial activities, as in claim 44, since bad odor is the result of bacterial or microbial actions (see column 1, lines 23-35, in particular.)

Komp does not expressly disclose the employment of the anionic surfactants such as those in claim 37 and 42; chelating agent such as EDTA as in claim 34; or the particular acid as in claim 35, added in the deodorant or antimicrobial or antibacterial compositions therein. Komp also does not expressly disclose the employment of a kit comprising the composition, as recited for example in claim 41.

Andrew et al (5,460,833) discloses a similar antimicrobial composition comprising similar ingredients as in Komp's composition, (i) the instant fatty acid monoester such as glycerol monolaurate, propylene glycol monolaurate, glycerol and propylene glycol

monoesters of caprylic and capric acids in amounts within the instant claim, (ii) the instant enhancers in amounts within the instant claim and further comprising a chelating agent EDTA, as in claim 34, and the instant organic acid such as lactic acid, tartaric acid, adipic acid, succinic acid, and citric acid, as in claim 35, and (iii) a food grad surfactant, including anionic surfactants such as dioctyl sodium sulfosuccinate and sodium laurylsulfate, as in claims 37 and 42; and a vehicle, i.e. water and/or particular alcohols such as propylene glycol and polyethylene glycol, or an aqueous solution and ethanol (see abstract, column 2, lines 38-55, column 3, lines 1-8 and 35-38, column 4, lines 36-62, column 5, lines 4-13 and 20-39, and claims 1-9, in particular.) Andrews et al. particularly discloses the components (i), (ii) and (iii) used together in the composition therein provide synergistic antimicrobial activity, compared to the substances when used alone under the same conditions (see column 2, lines 55-57 and column 3, lines 54-57, in particular.) Hence, each of the three major components alone is known to have antimicrobial activity. Andrews et al. also teaches that organic acids including the acids employed therein are know antimicrobial agents (see column 1, line 67 to column 2 line 7, in particular.) Andrews et al. further discloses the compositions therein are prepared by mixing the ingredients in a particular order (see column 5, line 41 through column 6, line 5.)

Accordingly, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the anionic surfactants such as dioctyl sodium sulfosuccinate and sodium laurylsulfate; a chelating agent such as EDTA; the

particular alcohol such as ethanol, the particular acid such as lactic acid, tartaric acid, adipic acid, succinic acid and/or citric acid in the deodorant or antimicrobial or antibacterial compositions of Komp.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the anionic surfactants such as dioctyl sodium sulfosuccinate and sodium laurylsulfate; a chelating agent such as EDTA; the particular alcohol, ethanol; the particular acid such as lactic acid, tartaric acid, adipic acid, succinic acid, citric acid, in the deodorant or antimicrobial or antibacterial compositions of Komp, since Komp and Andrews et al. clearly disclose all ingredients as instantly claimed used in the deodorant or antimicrobial or antibacterial compositions. In particular, the composition of Komp is known to comprise all the same essential and critical ingredients as instantly claimed, (i) the instant fatty acid monoester, glyceryl laurate in 0.5-5 wt% or 0.5-1.5 wt %, within the claimed range herein, (ii) the instant enhancer, benzoic acid in 0.1-0.5, touching the claimed range herein; surfactants in 2.0-10 wt %, overlapping the claimed range herein; a vehicle such as water in 0.1-50 wt %, or alcohols, and further comprising an acid such as citric acid.

Therefore, one of ordinary skill in the art would have found it obvious to employ the particular anionic surfactants such as dioctyl sodium sulfosuccinate and sodium laurylsulfate; a chelating agent such as EDTA; the particular alcohol, ethanol; the particular acid such as lactic acid, tartaric acid, adipic acid, succinic acid, and citric acid

in the deodorant or antimicrobial or antibacterial compositions, since all of these agents are known and art-recognized surfactants, chelating agents, alcohols and acids and are also known to be used in the similar antimicrobial or antibacterial compositions of Andrews et al.

Furthermore, one of ordinary skill in the art would have been motivated to prepare a kit comprising the same composition because the preparation of a kit comprising containers containing ingredients of a composition is considered well within the competence level of an ordinary skilled artisan in the pharmaceutical sciences, involving merely routine skill in the art, based on the preparation of the compositions disclosed by Andrews wt al. and Komp.

Claims 33, 35-37, 39, 41-51 and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,968,539 to Beerse et al (of record.)

Beerse et al. discloses an antimicrobial composition comprising (i) an antimicrobial active including glyceryl laurate (as in claim 43) (see column 5, line 20, in particular) in 0.0001-5 wt % (see also abstract, in particular), which overlaps with the range claimed herein; (ii) the anionic surfactants herein in an amount of 1-80 wt % (see column 8, line 41 through column 9, line 45 and column 2, lines 36-40 and 64, in particular), as in claims 37 and 42 and in a range that overlaps with the ranges in claims 52-54; a vehicle such as water in an amount of 3-98.8 wt% (a diluent, as in claim 45)

(see column 2, line 38, in particular); (iii) a proton donating agent, an organic acid such as salicylic acid (enhancer) as well as, tartaric acid, adipic acid, succinic acid and citric acid, as in claims 33 and 35, in 0.1-12 wt%, thus overlapping with the range recited herein (see abstract, column 14, lines 61-54, in particular); and ethanol, as in claims 33, 36 and 39 (see claims 1-19 and Examples at columns 24-28, in particular.) Accordingly, Beerse et al teaches a composition with antimicrobial and antibacterial effects, as recited in the claims and in claim 44.

Beerse et al. does not expressly exemplify the composition comprising the specific agents, glyceryl laurate and salicylic acid, as instantly claimed. Beerse et al. also does not expressly disclose the employment of a kit for the composition therein.

However, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the specific agents, glyceryl laurate and salicylic acid, in the antimicrobial or antibacterial compositions of Beerse et al.

One having ordinary skill in the art at the time the invention was made would have been motivated to provide the specific agents, glyceryl laurate and salicylic acid, in the antimicrobial or antibacterial compositions of the prior art, since Beerse et al. provides a reasonable expectation of success for all antimicrobial actives listed in the patent, including glyceryl laurate, all organic acids including salicylic acid, tartaric acid, adipic acid, succinic acid, and citric acid, as used in the antibacterial compositions

therein, even though Beerse et al. does not exemplify glyceryl laurate and salicylic acid as preferred agents. It has been well-established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to a person of ordinary skill in the art. In re Boe, 355 F.2d 961, 148 USPQ 507, 510 (CCPA 1966); In re Lamberti, 545 F.2d 747, 750, 192 USPQ 279, 280 (CCPA 1976); In re Fracalossi, 681 F.2d 792, 794, 215 USPQ 69, 570 (CCPA 1982); In re Kaslow, 707 F.2d 1366, 1374, 217 USPQ 1089, 1095 (Fed. Cir. 1983.)

Therefore, the motivation provided by the cited prior art herein to make the present invention is clearly present.

Furthermore, one of ordinary skill in the art would have been motivated to prepare a kit comprising the same composition because the preparation of a kit comprising containers containing ingredients of a composition is considered well within the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art, based on the preparation of the compositions disclosed by Beerse et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 33-37, 39-45 and 52-54 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/659,571.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to the same or substantially the same antimicrobial composition comprising the same or substantially same ingredients in the same or substantially same amounts.

Thus, the instant claims are seen to be obvious over the claims 1-21 of copending Application No. 10/659,571.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 33-37, 39-45 and 52-54 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 10/936,989.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to the same or substantially the same antimicrobial composition or kit comprising the same or substantially the same ingredients in the same or substantially same amounts.

Thus, the instant claims are seen to be obvious over the claims 1-25 of copending Application No. 10/936,989.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 33-37, 39-45 and 52-54 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/937,059.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to the same or substantially the same antimicrobial composition or kit comprising the same or substantially the same ingredients in the same or substantially the same amounts.

Thus, the instant claims are seen to be obvious over the claims 1-25 of copending Application No. 10/937,059.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have yet to be patented.

Response to Arguments

Applicant's arguments filed November 16, 2005, have been fully considered but they are not persuasive.

In particular, Applicant's argue that the references do not teach a kit comprises first and second containers, a claimed. However, as discussed above, providing the

ingredients in containers and as a part of a kit is well known and is well within the competence level of one of ordinary skill in the art. Accordingly, one of ordinary skill in the art would find it obvious to provide a "kit" having a first container with the fatty acid monoester, and a second container with the enhancer, such as for example first and second containers that comprise bottles in which the ingredients are received from a commercial vendor, or a container that is used to mix the ingredients together to form the antibacterial or antimicrobial composition as taught in the prior art.

It is furthermore, noted, as discussed above, that Andrews et al (5,460,833) teaches forming a first solution of a composition comprising a surfactant and the antimicrobial acid, and a second composition comprising the glycerol monolaurate (with dioctyl sodium sulfosuccinate optionally added to either of the first and second solutions), and then combining the two (see column 5, lines 40-60, in particular), and thus necessarily teaches providing at least two containers to hold the first and second solutions before combining. Accordingly, the kit comprising the first and second containers having the ingredients is obvious over the cited prior art.

The 35 U.S.C. 132 Declaration filed by Applicants on November 16, 2005 and signed by Matthew T. Scholz has been fully considered, but is not found persuasive to overcome the rejections of record.

In particular, the declaration compares the relative % content of a composition at an initial point, after 3 weeks, and following 6 weeks of compositions prepared with fatty acid monoesters (i.e. propylene glycol monocaprylate and glycerol monolaurate) and with or without enhancers (i.e. benzoic acid and salicylic acid.) The declaration also compares the change in the relative percent content between such compositions prepared with an anhydrous vehicle, such as glycerin and propylene glycol (Table I), and compositions prepared with an aqueous vehicle (Table II.)

The declaration states that the compositions without the enhancer are stable, with little or no change in the % content of the composition the addition of the enhancer to the formulas results in the generation of products. The addition of enhancer to the anhydrous composition resulted in a slight increase in PGMC8 and a slight decrease in PGDC8 (see bullet point 7, in particular.) The declaration further states that the higher level of PGMC8 is expected to provide a more active composition with improved antimicrobial efficacy (see bullet point 7, in particular.) However, Applicant's do not provide any evidence that the resulting composition has unexpectedly good activity over the prior art compositions as taught by Komp et al, Andrews et al. and Beerse et al. It should be noted that a showing of unexpected results must be based on evidence, not argument or speculation. In re Mayne, 104 F.3d 1339, 1343-44, 41 USPQ2d 1451, 1455-56 (Fed. Cir. 1997.)

The declaration further stated that addition of the enhancer to the aqueous composition significantly decreases the stability of composition and results in a dramatic and rapid loss of the antimicrobial fatty acid monoester component (see bullet point 7, second full paragraph, in particular.) However, as discussed similarly above, this statement is not considered to show unexpectedly good results for the claimed composition over the prior art of record, namely Komp et al, Andrews et al. and Beerse et al, and in particular does not show unexpectedly good antimicrobial activity over the prior art compositions.

Furthermore, should Applicant's intend to show unexpectedly good results for anhydrous compositions over aqueous compositions, it is noted that evidence of unexpected results is required to be reasonably commensurate in scope with the claimed invention. See, e.g., In re Kulling, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990); In re Grasselli, 713 F.2d 731, 743, 218 USPQ 769, 777 (Fed. Cir. 1983). The claimed invention as recited in claim 41 recites a vehicle in general, and thus reads on all vehicles including both aqueous and anhydrous, and is not restricted to only those compositions having an anhydrous vehicle.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER